DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Amedica® Corporation
% Justin Eggleton
Director, Spine Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors, LLC
1331 H Street, Northwest 12th Floor
Washington DC, 20005

December 8, 2014

Re: K142264
Trade/Device Name: Valeo™ Spacer System, Valeo™ II Interbody Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: September 8, 2014
Received: September 9, 2014

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director,
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142264

Device Name
Valeo™ Spacer System and Valeo™ II Interbody Fusion Device System

Indications for Use *(Describe)*
Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to the C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo™ Spacer System-L and Valeo™ II Interbody Fusion Device System - Lumbar are indicated for use with autograft bone graft in patients with DDD at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Valeo™ Spacer System-L and Valeo™ II Interbody Fusion Device System - Lumbar are intended to be used with supplemental spinal fixation systems, such as Preference Pedicle Screw System. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Device Trade Name: Valeo™ Spacer System (Valeo™ Spacer System –C and Valeo™ Spacer System –L)
Valeo™ II Interbody Fusion Device System (Valeo™ II Interbody Fusion Device System –Cervical and Valeo™ II Interbody Fusion Device System – Lumbar)

Manufacturer: AMEDICA® Corporation
1885 West 2100 South
Salt Lake City, UT 84119
Phone: (855) 839-3500

Contact: Mr. William D. Jordan
Senior Director Regulatory Affairs and Quality Assurance

Prepared by: Mr. Justin Eggleton
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Phone: (202) 552-5800
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Date Prepared: December 5, 2014

Classifications: 21 CFR §888.3080, Intervertebral Body Fusion Device

Class: II

Product Codes: MAX, ODP

Indications For Use:
Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level or two contiguous levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach from the C2-C3 disc space to the C7-T1 disc space using autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Valeo™ Spacer System-L and Valeo™ II Interbody Fusion Device System - Lumbar are indicated for use with autograft bone graft in patients with DDD at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Valeo™ Spacer System-L and Valeo™ II Interbody Fusion Device System - Lumbar are intended to be used with supplemental spinal fixation systems, such as Preference Pedicle Screw System. Patients should be skeletally mature and have six months of non-operative therapy prior to treatment with an intervertebral cage.

Device Description:
The Valeo™ Spacer System and Valeo™ II Interbody Fusion Device System devices consist of a variety of hollow intervertebral body spacers featuring convex, bullet nose design and an axial void designed to hold bone graft material per the indications stated above. The subject device is offered in various geometries to accommodate different surgical approaches and vertebral body dimensions. The subject devices are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical is manufactured from MC_2 ceramic material (silicon nitride), and is provided sterile.

The purpose of the subject 510(k) was to expand the indications of the Valeo™ Spacer System-C and Valeo™ II Interbody Fusion Device System –Cervical devices to include use with allograft and use at two contiguous levels from C2/C3 to C7/T1.

Predicate Device:
The modifications to the Valeo™ Spacer System and Valeo™ II Interbody Fusion Device System are substantially equivalent to the predicate ANATOMIC PEEK™ Cervical FUSION SYSTEM (K130177) with respect to indications, design, and performance.

Substantial Equivalence:
The Valeo™ Spacer System and Valeo™ II Interbody Fusion Device System and predicate ANATOMIC PEEK™ Cervical FUSION SYSTEM are similar in design and indicated use, and are both cleared devices. They do differ in that the ANATOMIC PEEK™ is indicated for use with allogenic bone graft. A comprehensive clinical literature review was conducted to assess any additional safety concern for the use of this device at two cervical levels with the use of allograft. The review of the literature concluded that there were no additional risks due to the modification of indications for this device and that the device was substantially equivalent to the predicate device.

Conclusion:
This 510(k) was submitted on behalf of the Valeo™ Spacer System and Valeo™ II Interbody Fusion Device System (cervical interbody cages only) to expand the indications for use to include use with allograft and use at two contiguous levels from C2/C3 to C7/T1. Substantial equivalence was determined in response to sufficient comparisons to a predicate device.